REMARKS

Claims 8, 9, 14, 15, 18, 19, 23, 24 and 26-45 are pending in the instant application. Correction of Form PTOL-326 and the Office Action mailed May 18, 2007 indicating claims 8, 9,14, 15, 18, 19, 23, 24 and 26 to be pending and claims 8, 9, 14, 15, 18, 19, 23, 24 and 26-24 to be rejected is respectfully requested. Reconsideration of the rejection of the pending claims is respectfully requested in light of the following remarks and additional information provided herewith.

Rejection of Claims 8, 9, 13-15, 17-19, 21, 23, 24 and 26-45 under 35 U.S.C. 112, first paragraph - Lack of Enablement

Claims 8, 9, 14, 15, 18, 19, 23, 24 and 26-45 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The Examiner suggests that that specification reasonably communicates that the native protein expressed by SEQ ID NO:1 is Pro104 which is the instant SEQ ID NO:2 protein. The Examiner suggests that the specification as originally filed does not reasonably communicate that the protein known in the art as testisin is the same as the

instantly claimed Pro104. According to the Examiner, sequence alignment shows SEQ ID NO:2 is not the same as testisin. Thus, the Examiner suggests that what is taught by Tang et al. and Papkoff et al. is not germane to the analysis of enablement of the instant claimed invention.

The Examiner also suggests that the instant specification has failed to teach with a reasonable certainty that the protein encoded by SEQ ID NO:1 is a gynecologic cancer antigen while the art (Hooper et al.) suggests that the protein encoded by SEQ ID NO:1 is a tumor suppressor.

Applicants traverse this rejection.

At the outset, it is respectfully pointed out that the pending claims are directed to methods of use of an antibody that specifically binds "the native protein expressed by SEQ ID NO: 1". This claim language is clearly supported by teachings in the specification at page 4, line 26 through 28 and page 7, line 34 through page 8, line 2. The claims do not refer to SEQ ID NO:2. It is these claims, drawn to methods of use of an antibody that specifically binds "the native protein expressed by SEQ ID NO: 1" which must be enabled. See MPEP 2164.

Further, Applicants respectfully disagree with the Examiner's characterization of the specification as reasonably communicating that "the native protein expressed by SEQ ID NO:1 is "Pro104" which is the instant SEQ ID NO:2 protein." Instead, the specification, at page 4, lines 28 through 30 and page 8, lines 2 through 4, teaches that SEQ ID NO:2 depicts an amino acid sequence of a polypeptide ***encoded*** [emphasis added] by SEQ ID NO:1, and not necessarily the ***native protein expressed*** [emphasis added] by SEQ ID NO:1. Further, at page 25, lines 17-32 applicant's characterization of the Pro104 polypeptide does not teach that SEQ ID NO:2 is the native protein expressed by SEQ ID NO:1.

Applicants also respectfully disagree with the Examiner's characterization of the Office Action mailed 4/21/2004 as part of the prosecution history indicating that "the native protein expressed by SEQ ID NO:1 is "Pro104" which is the instant SEQ ID NO:2 protein". Instead, at page 4 of the Office Action mailed 4/21/2004 the Examiner states that:

> The specification at page 18, lines 15 and page 25, lines 17-18 implies that 'a Pro104 polypeptide' is ***either*** [emphasis added] SEQ ID NO:2 ***or*** [emphasis

> added] protein encoded by SEQ ID NO:1 with Clone ID 1450626 and Gene ID 236019.

Further on that page of the April 21, 2004 Office Action the Examiner states that:

> It appears that the specification limit "Pro104" to SEQ ID NO:1 ***or*** [emphasis added] the protein encoded by SEQ ID NO:1 with Clone ID 1450626 and Gene ID 236019.

Finally at page 10 of the Office Action the Examiner states that the Office's interpretations to be:

> that the instant SEQ ID NO:1 encoded the art-known protein, lacking the first 13 amino acids of instant SEQ ID NO:2.

There the Examiner acknowledged that it was known from teachings of Darnell et al. that any in vivo translated protein has Met as the first amino acid and that SEQ ID NO:2 and that since SEQ ID NO:2 starts with an Arg it is not the protein expressed in vivo by SEQ ID NO:1. In addition, as already pointed out in the response filed July 17, 2006, the first ATG of SEQ ID NO:1 has a flanking sequence, GAGGCCATGG, which meets the requirements for an initiator codon as identified by the Kozak eukaryotic sequence.

Nor did Applicants response in any way imply or suggest that "the native protein expressed by SEQ ID NO:1 is "Pro104" which is the instant SEQ ID NO:2 protein". Instead, the response filed by Applicants on August 23,

2004 stated that "Applicants in no way assert that the polypeptide encoded by SEQ ID NO;1 and depicted in the instant application as SEQ ID NO:2 is a "protein existing in vivo"."

Therefore, the Examiner's suggestion that "the native protein expressed by SEQ ID NO:1 is Pro104, which is the instant SEQ ID NO:2", is improper since it is contradiction of the teachings of the specification and the Examiner's own characterization/interpretation of the specification.

The Examiner has previously presented a sequence alignment (Exhibit A) to assert the Examiner's assertion that SEQ ID NO:2 is not the same as testisin, and therefore, the confirmatory teachings of Tang et al. and Papkoff et al. are not germane to the instantly claimed invention.

As already discussed above, the instant claimed invention is directed to use of an antibody that specifically binds "the native protein expressed by SEQ ID NO: 1". The claims do not refer to SEQ ID NO:2. Applicants are submitting herewith a sequence alignment demonstrating that testisin (Q9Y6M0 from Examiner's alignment) is the native protein expressed by SEQ ID NO:1, or, as acknowledged by the Examiner in the 4/21/04 Office Action, the art-known protein encoded by SEQ ID NO:1 lacking the first amino acids of instant SEQ ID NO:2.

Therefore, contrary to the Examiner's suggestion, the confirmatory teaching of Tang et al. and Papkoff et al. relating to testisin are germane to the instantly claimed invention, namely a method of use of an antibody that specifically binds "the native protein expressed by SEQ ID NO: 1" . Specifically, frames 5, 6, 7, 8 and 9 of Papkoff et al. show *images* of cells contacted with an antibody which specifically binds the native protein expressed by SEQ ID NO:1, directly rebutting the Examiner's mischaracterization that Papkoff et al. does not establish if one could image gynecologic cancers.

MPEP 2164.05 is clear; the examiner should **never** make the determination based on personal opinion. Instead, the examiner must weigh all the evidence before him or her, including the specification and any new evidence supplied by applicant with the evidence and/or sound scientific reasoning previously presented in the rejection to decide whether the claimed invention is enabled.

Based on the teaching of the specification, the level of skill in the art at the time of filing, sound scientific reasoning acknowledged by the Examiner to exist with respect to identifying proteins expressed in vivo as well as the Kozak et al. publications provided by Applicants, and the confirmatory teachings of Tang et al. and Papkoff

et al., the pending claims of the instant invention are fully enabled for one of skill in the art.

Withdrawal of the rejection under 35 U.S.C. 112, first paragraph is therefore respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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